



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,074	02/03/2004	Joel F. Zuhars	137782 (MHM - 15221US01)	1973
23446 7590 01/23/2009 MCANDREWS HELD & MALLOY, LTD 500 WEST MADISON STREET SUITE 3400 CHICAGO, IL 60661			EXAMINER BITAR, NANCY	
			ART UNIT 2624	PAPER NUMBER
			MAIL DATE 01/23/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/771,074	Applicant(s) ZUHARS ET AL.	
	Examiner NANCY BITAR	Art Unit 2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/16/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

1. Applicant's arguments, in the amendment filed 09/30/2008, with respect to the rejections of claims 1-3, 5-20 under 35 U.S.C. 103(a) have been fully considered but are moot in view of the new ground(s) of rejection necessitated by the amendments. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Jensen et al (US 6,666,579) and Hunter et al (US 2004/0152972)
2. Claims 1-3, 5-20 are currently pending.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim(s) **1-17** are rejected under 35 U.S.C. 101 as not falling within one of the four statutory categories of invention. While the claims recite a series of steps or acts to be performed, a statutory “process” under 35 U.S.C. 101 must (1) be tied to another statutory category (such as a particular apparatus), or (2) transform underlying subject matter (such as an article or material) to a different state or thing (Reference the May 15, 2008 memorandum issued by Deputy Commissioner for Patent Examining Policy, John J. Love, titled “Clarification of ‘Processes’ under 35 U.S.C. 101”). The instant claims neither transform underlying subject matter nor positively tie to another statutory category that accomplishes the claimed method steps, and therefore do not qualify as a statutory process

NOTE: Regarding the rejection of claims 1-17, please see the Memorandum dated May 15, 2008, "Clarification of Processes under 35 USC § 101" which may be viewed at the following web address:

http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/section101_05_15_2008.pdf

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3,5-20 are rejected under 35 U.S.C. 103(a) as being anticipated by Jensen et al (US 6,666,579) in view of Hunter et al (2004/0152972).

As to claim 1, Jensen et al. teaches a method of performing instrument tracking on an image comprising:

collecting a plurality of static images (a C-arm unit having an x-ray source for generating x-rays and a receptor for obtaining image exposures from received x-rays, the C-arm capable of moving the x-ray source and receptor along an image acquisition path between at least first and second exposure positions; figure 1; note that The image processing computer 16 collects a series of image exposures 32 from the receptor 34 as the C-arm 12 is rotated);

computing at least one of a position and orientation of at least one instrument for said plurality of static images (the tracker module 18 receives position information from receptor,

Art Unit: 2624

patient and instrument position sensors 40, 42 and 44, respectively, figure 1; note that the C-arm may be manually, mechanically or automatically moved along the image acquisition path.); and

automatically displaying each image in said collected plurality of static images in an image by image manner to create an animation, wherein said at least one position and orientation of said at least one instrument is projected on each said image (The display graphics processor 295 accesses the slice data set memory 290 to display the image slices on the display 250. The display graphics processor 295 also constructs graphical representations of the instrument or tool 24 and overlays the instrument graphic with the image slices on the display 250. The display graphics processor 295 may present multiple two-dimensional image slices simultaneously on the display 250 with instrument graphics superimposed upon each image slice, column 10, lines 25-50). While Jensen meets a number of the limitations of the claimed invention, as pointed out more fully above, Jensen does not specifically teach the images are static. Specifically, Hunter et al. teaches the image-based procedure by employing a localization or navigation tracking system or capturing image data, wherein the imaging device 16 may be employed to either simply gather static image data or image data over time. Moreover, Hunter et al teaches at block 240, the data from either the image based or the image sense based pre-operative planning is analyzed. Should the data only include image data from block 238, this image data may be used to identify areas of interest, the patient size, and be used to assist in preparing the surgical plan. By viewing this data, such as 4D data, which is essentially 3D data over time or static image data, certain abnormal or irregular movements in the area of interest may be identified. These areas may be identified by visual examination, by performing finite element analysis or other known motion analysis to create a 3D model of the captured image. It would have been obvious

Art Unit: 2624

to one of ordinary skill in the art to use the static image based procedure or the static sensor based procedure of Hunter in Jensen et al in order to identify points of interest or potential abnormal activities by sensing parameters, such as temperature, pressure, stress, and strain in the area of interest thus registering a more accurate tracking. Therefore, the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention by applicant.

As to claim 2, Jensen et al. teaches the method of claim 1 wherein said plurality of images comprise a plurality of 2D fluoroscopic images (the acquisition module acquires a sequence of 2D fluoroscopic images at a predetermined positions spaced along the imaging path. Optionally the acquisition module may obtain 2D fluoroscopic images at an even interval along the image acquisition path, column 3, lines 44-55).

As to claim 3, Jensen et al. teaches the method of claim 2 comprising continuously presenting the image by image animation using a display (The display graphics processor 295 also constructs graphical representations of the instrument or tool 24 and overlays the instrument graphic with the image slices on the display 250. The display graphics processor 295 may present multiple two-dimensional image slices simultaneously on the display 250 with instrument graphics superimposed upon each image slice. Alternatively or in combination with image slices, the display graphics processor 295 may construct a three-dimensional rendering of the 3-D patient data volume and display the three-dimensional rendering on the display 250 separately or in combination with a three-dimensional graphical representation of the instrument 24, figure 7).

As to claim 5, Jensen et al. teaches the method of claim 1 comprising calibrating at least one image of said collected plurality of images such that said at least one position and orientation

Art Unit: 2624

of said at least one image may be accurately displayed (a display graphics processor 295 in the image processing computer 16 construct graphical representation of the instrument or tool 24, the display graphic processor 295 may also present multiple two dimensional image sliced simultaneously on the display 250 with instrument graphics superimposed upon each slice , column 9, lines 66-column 10, lines 1-65)).

As to claim 6, Jensen et al. teaches the method of claim 5 comprising selecting at least one calibrated image to be a current image (The display graphics processor 295 may present multiple two-dimensional image slices simultaneously on the display 250 with instrument graphics superimposed upon each image slice. Alternatively or in combination with image slices, the display graphics processor 295 may construct a three-dimensional rendering of the 3-D patient data volume and display the three-dimensional rendering on the display 250 separately or in combination with a three-dimensional graphical representation of the instrument 24, column 10, lines 25-49).

As to claim 7, Jensen et al. teaches the method of claim 6 comprising computing said at least one position and orientation for said at least one instrument for said current image (FIG. 1, the tracker module 18 receives position information from receptor, patient and instrument position sensors 40, 42 and 44, respectively, column 8, lines 33-66)

As to claim 8, Jensen et al. teaches the method of claim 1 comprising collecting said plurality of images using at least one moveable collection device (the C-arm 12 is movable in several directions along multiple images acquisition paths , column 3, lines 19-60).

As to claim 9, Jensen et al. teaches the method of claim 8 wherein said moveable collection device comprises a C-arm coupled to an imaging device (a C-arm 12 and an image processing computer 16 , figure 1)

The limitation of claim 10 has been addressed above except for the following “automatically repeating said selecting, computing and projecting and displaying steps to create an animation using a sequential image by image presentation through said series of 2D images”. Jensen teaches that limitation in (the image processing computer 16 repeats steps 305-340 as shown in figure 8 so as to improve upon the patient slices imaged being displaced)

As to claim 11, Jensen et al. teaches the method of claim 10 comprising collecting said series of 2D images using a collection device that moves (the C-arm is moved through an image acquisition path (A, B), along which at least first and second images are obtained. An acquisition module obtains multiple 2-D fluoroscopic images at desired positions along the image acquisition path and an image processor constructs a 3-D volume of object data based on the 2-D fluoroscopic images, see abstract)

As to claim 12, Jensen et al. teaches the method of claim 11, wherein said collection device comprises a C-arm coupled to the imaging device (image processing computer 16 connected to the receptor device 34, figure 1).

As to claim 13, Jensen et al. teaches the method of claim 10 wherein said series of 2D images comprise a series of 2D fluoroscopic images (2D fluoroscopic images , column 3 , lines 1-17).

As to claim 14, Jensen et al. teaches the method of claim 10 comprising continually using said sequential image presentation by image through said series of 2D images in a display (A

Art Unit: 2624

fluoroscopy imaging system 200 includes a detector 210 mounted to a C-arm for detecting x-rays passed through a patient. A tracking subsystem 220 receives patient coordinate information 225, detector coordinate information 230 and instrument coordinate information 235. The tracking subsystem 220 processes the coordinate information 225-235 and passes it to an image processing unit 240 which receives exposure frames from the detector 210 and outputs image frames to the display 250, figure 7).

As to claim 15, Jensen et al. teaches the method of claim 14 comprising projecting said at least one position and orientation of said at least one instrument into at least one image of said series of 2D images (the image processor may perform an iterative reconstruction technique to construct the 3-D volume. Alternatively, the image processor may perform a back projection technique to construct the 3-D volume, column 3, lines 19-26)

As to claims 16-17, Jensen et al. teaches the method of incrementing at least said current image and recomputing said at least one position and orientation of said at least one instrument (the 3-D patient data set is updated with the information from 10 or more exposures before patient slices are reconstructed. Additional exposures may be obtained, beyond 10 exposures by repeating steps 305-325, thereby improving the information within the 3-D patient data set. Once patient slices and/or 3-D images are constructed at step 335, the patient slices and/or 3-D images are displayed at step 340, alone or in combination with instrument graphics representing the position of the instrument 24 relative to the patient 22, column 11 ,lines 15-29) .

The limitation of claims 18-20 has been addressed .

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY BITAR whose telephone number is (571)270-1041. The examiner can normally be reached on Mon-Fri (7:30a.m. to 5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jinge Wu can be reached on 571-272-7429. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jingge Wu/
Supervisory Patent Examiner, Art Unit 2624

/Nancy Bitar/
Examiner, Art Unit 2624